

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PBAP89635PWO		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/GB2004/002527		International filing date (day/month/year) 11.06.2004	Priority date (day/month/year) 13.06.2003	
International Patent Classification (IPC) or national classification and IPC A61M35/00				
Applicant MEDLOGIC GLOBAL LIMITED et Al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  11.04.2005		Date of completion of this report  26.08.2005		
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Kousouretas, I Telephone No. +31 70 340-2449 		

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-9 filed with telefax on 29.07.2005

**Drawings, Sheets**

1/5-5/5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☒ the claims, Nos. 1
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 8,9

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 8,9

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-7
	No: Claims	
Inventive step (IS)	Yes: Claims	1-7
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-7
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item I**

The expression 'the tab stem passes through the pad' in claim 1 extends beyond the disclosure as filed. In fact, it is nowhere to be found in the original application that the stem can be moved within the pad from one side to the other through the channel. In paragraph 17 of the original application it is disclosed that the 'tab can be readily separated from the dispenser by pulling the stem through channel'. Therefore, for judging the patentability of claim 1 the expression 'the tab stem passes through the pad' has been interpreted as 'the tab stem can be pulled through the channel'.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document:

D1: GB-A-2 185 880 (CHESEBROUGH PONDS) 5 August 1987 (1987-08-05)

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (see page 1, line 91- page 2, line 9 and figure, the references in parentheses applying to this document):

An applicator comprising a reservoir, a pad in fluid communication with the reservoir and a tab serving to seal the fluid reservoir at a breakable connection, the reservoir comprises a flexible wall, the pad includes a channel and the breakable connection is formed of a friable material such that bending of the tab relative to the applicator causes breaking of the breakable connection to allow passage of fluid from the reservoir into the pad.

The subject-matter of claim 1 differs from this known from D1 in that the stem is slidably received into the pad and the tab stem can be pulled through the channel.

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The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as easy and safe use of the device, so that the fluid can be applied on any surface easily and at the same time the user will not run the risk of injury from the broken stem.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT), because the tab can be removed from the pad through the channel after breaking the connection with the reservoir.

Claims 2-7 are dependent on claim 1 and as such also meet/s the requirements of the PCT with respect to novelty and inventive step.

### Claims

1. An applicator comprising:  
a reservoir adapted to contain a fluid;  
a pad in fluid communication with the reservoir; and  
a tab serving to seal the fluid reservoir at a breakable connection,  
wherein the reservoir comprises a wall which is adapted to flex sufficiently under pressure from an operator's finger to force fluid from the reservoir into the pad, the tab includes a stem attached to the applicator at the breakable connection, the pad includes a channel for slidably receiving said stem, the tab stem passes through the pad, and the breakable connection is formed of friable material such that bending the of the tab relative to the applicator causes breaking of said breakable connection to allow passage of fluid from the reservoir into the pad.
2. The applicator of Claim 1, wherein the channel is oval in cross-section.
3. The applicator of Claim 1, wherein the fluid is a sterilizable liquid.
4. The applicator of Claim 1, wherein the fluid is a sterilizable tissue adhesive for surgical applications.
5. The applicator of Claim 1, wherein the fluid comprises a cyanoacrylate ester adhesive.
6. The applicator of Claim 1, wherein the fluid comprises butyl or octyl cyanoacrylate, or a mixture of butyl and octyl cyanoacrylates.
7. The applicator of Claim 1 wherein the removable tab has a twist-off portion that protrudes from the pad.
8. A method for applying a fluid onto mammalian skin which method comprises:
  - a) selecting an applicator comprising:  
a reservoir adapted to contain said fluid;  
a pad in fluid communication with the reservoir; and

a tab serving to seal the fluid reservoir at a breakable connection, wherein breaking of said breakable connection allows passage of fluid from the reservoir into the pad;

b) manipulating the tab thereby breaking the seal formed by the tab such that fluid in the reservoir flows into the pad; and

c) applying the fluid from the pad onto said skin. 1

9. A method for applying a fluid onto mammalian skin which method comprises:

a) selecting an applicator comprising:

a reservoir itself comprising a wall which flexes under pressure from an operator's finger and being adapted to contain said fluid;

a pad in fluid communication with the reservoir; and

a tab serving to seal the fluid reservoir at a breakable connection, wherein breaking of said breakable connection allows passage of fluid from the reservoir into the pad;

b) manipulating the tab thereby breaking the seal formed by the tab such that fluid in the reservoir flows into the pad;

c) applying finger pressure onto the flexible wall of the reservoir to cause it to flex sufficiently to force fluid from the reservoir into the pad; and

d) applying the fluid from the pad onto said skin.